

ARTHROCARE MAXIMUM ARTHRITIS PAIN RELIEF- methyl salicylate, lidocaine cream

Patient Focused Telehealth, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredients

Methyl Salicylate 15%

Lidocaine 4%

Purpose

Topical Analgesic

Use

For temporary relief of minor aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- joint pain

Warnings

For external use only

Use only as directed. Read and follow all directions and warnings on this carton.

Avoid contact with eyes and mucous membranes.

Do not use

- at the same time as other topical analgesics
- on open wounds, cuts, damaged or infected skin
- with bandage or heating pad

Consult Doctor before use

Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- If pregnant or breast-feeding or if you have sensitive skin, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Directions

- Apply 3 to 6 drops of product directly to affected area
- Product may be used as necessary, but should not be used more than four times per day
- Gently massage the product for 15 - 30 seconds into the skin over the site of pain (joint or muscle)

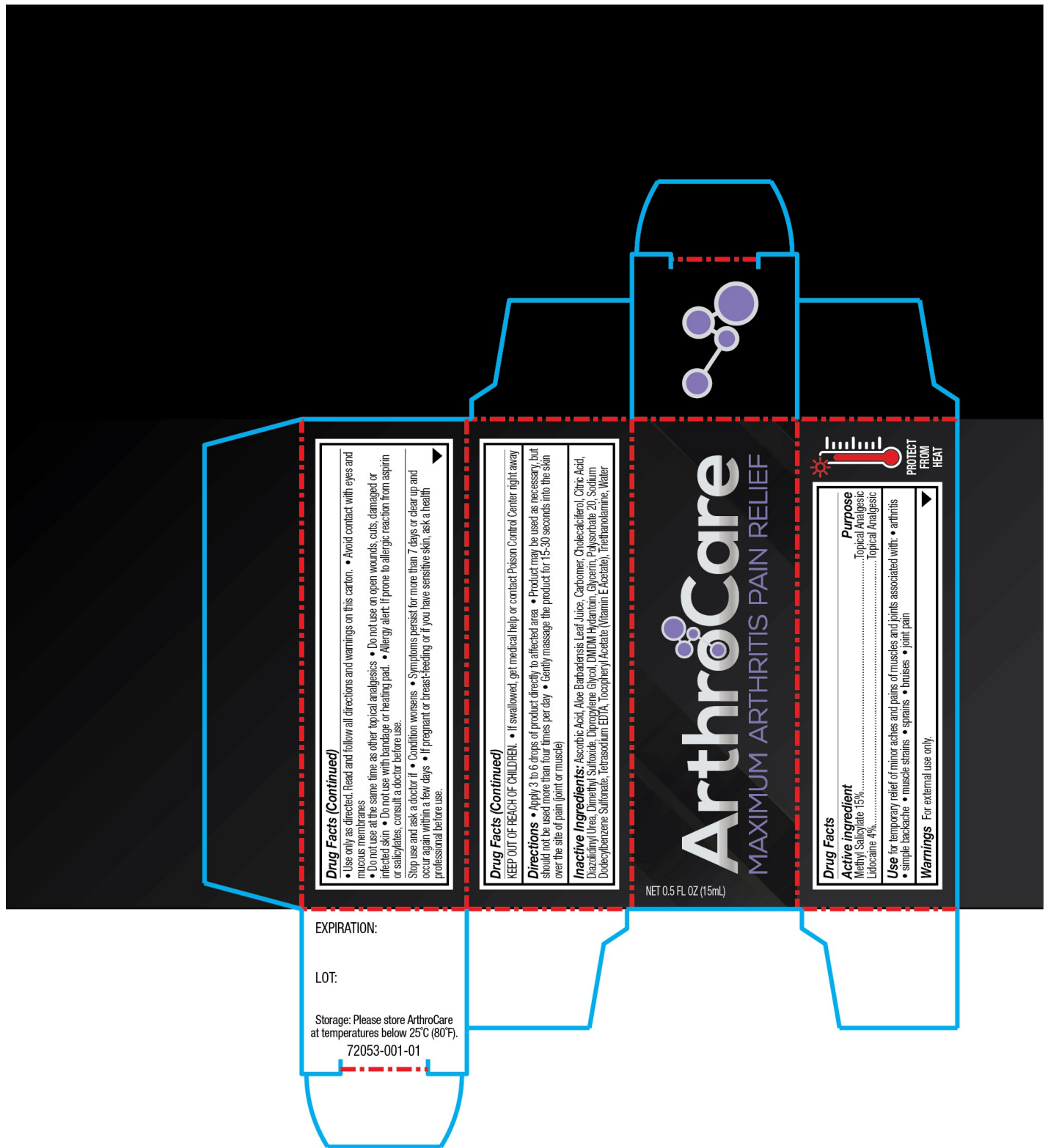
Inactive Ingredients

Ascorbic acid, aloe barbadensis leaf juice, carbomer, cholecalciferol, citric acid, diazolidinyl urea, dimethyl sulfoxide, dipropylene glycol, DMDM hydantoin, glycerin, polysorbate 20, sodium dodecylbenzene sulfonate, tetrasodium EDTA, tocopheryl acetate (vitamin E acetate), triethanolamine, water

Principal Display Panel

Arthrocare Maxium Arthritis Pain Relief

Net 0.5 fl oz (15 ml)



ARTHROCORE MAXIMUM ARTHRITIS PAIN RELIEF

methyl salicylate, lidocaine cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72053-001	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)		METHYL SALICYLATE	337.5 mg in 15 mL	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	24 mg in 15 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ASCORBIC ACID (UNII: PQ6CK8PD0R)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0KO0R)				
EDETATE SODIUM (UNII: MP1J8420LU)				
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CHOLECALCIFEROL (UNII: 1C6V77QF41)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
DIPROPYLENE GLYCOL (UNII: E107L85C40)				
DMDM HYDANTOIN (UNII: BYR0546TOW)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)				
GLYCERIN (UNII: PDC6A3C0OX)				
TROLAMINE (UNII: 9O3K93S3TK)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72053-001-01	1 in 1 BOX	10/19/2021	
1		15 mL in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part348	10/19/2021	

Labeler - Patient Focused Telehealth, LLC (081008911)

Registrant - Patient Focused Telehealth, LLC (081008911)

Establishment

Name	Address	ID/FEI	Business Operations
TG Labs		831504621	manufacture(72053-001)

Revised: 10/2021

Patient Focused Telehealth, LLC